Government of India
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National Good Laboratory Practice (GLP) Compliance Monitoring Authority

TERMS & CONDITIONS OF NGCMA FOR OBTAINING AND MAINTAINING GLP CERTIFICATION BY A TEST FACILITY

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TERMS & CONDITIONS OF NGCMA FOR OBTAINING AND MAINTAINING GLP CERTIFICATION BY A TEST FACILITY

1. A Test Facility (TF) desirous of obtaining a GLP compliance status, called "GLP Certificate" from the National GLP Compliance Monitoring Authority (NGCMA) shall submit an application in the prescribed Application Form (GLP-102), along with the non-refundable prescribed fee by way of a demand draft drawn in favour of 'Quality Council of India' payable at New Delhi, to:

   GLP Cell
   Quality Council of India
   Institution of engineers building
   2nd Floor, Bahadur Shah Zafar Marg
   New Delhi-110002
   Telephone: +91-11- 2337 9321, 2337 8056
   Fax: +91-11-2337 8678
   email: glpindia@qcin.org

2. Copies of all documents (e.g., organizational charts, floor plans, master schedule etc.), to be enclosed with the application should be authenticated with dated signatures by the Test Facility Management (TFM).

3. A TF is eligible for seeking GLP certification, if it is involved in conducting scientific study or research related to non-clinical health or environmental safety studies. Such TFs can be:
   a) Contract Research Organization
   b) R & D institution
   c) University/ Deemed to be University/ Institute of National Importance
   d) Industry/ Company
   e) Government organization/ Public Sector Enterprise

4. The applicant TF shall provide access to its records and facilities, as applicable under the scope of GLP certification, for inspections by NGCMA.

5. If the GLP application is found complete and eligibility criteria for GLP certification are met, NGCMA will organize TF inspection i.e. an on-site examination of the TF's procedures and practices to assess compliance with OECD Principles of GLP.

6. Inspections conducted by NGCMA are categorized as:

   a. **Inspections for obtaining GLP certification:** Pre-inspection, Final inspection, Extension in scope inspection and Verification inspection, wherever applicable.

b. **Inspections for maintaining GLP certification:** Surveillance inspection, Inspection for Re-certification and Verification inspection, wherever applicable.

c. **Other inspections:** Surprise inspection, Inspection/ Joint inspection conducted at the request of GLP Compliance Monitoring Authorities (CMAs) or Regulatory Authority (RA) of OECD Mutual Acceptance of Data (MAD) adherent countries or Indian RA.

All the above mentioned inspections are defined in Document No. GLP-111 "Definitions of General Terms Used in NGCMA" and GLP-104 "Procedures of NGCMA Secretariat".

7. For conducting a TF inspection, a team of inspectors will be appointed by Head, NGCMA. Inspection planning will be carried out as per the procedure specified in Document No. GLP-109 "Scheduling of GLP Inspections by NGCMA". However, all inspections will be conducted at dates mutually convenient to both the inspection team and the TF. A communication of inspection team and dates would be sent to the respective TF by NGCMA. If the TF has reservation on the inspection team or any member, it may indicate the same to NGCMA immediately on the receipt of communication along with valid reasons. If no communication is received from the TF, it shall be assumed that the inspection team is acceptable to the TF. All information received with respect to the TF will be kept confidential by the NGCMA and its inspectors.

8. GLP certification awarded to a TF will be valid for a period of three years, unless otherwise revoked in consonance with the Document No. 113 "Policies and procedures of NGCMA for taking adverse and other decisions against test facilities". This three-year period, subject to continued compliance to OECD Principles of GLP, shall be termed as a GLP certification cycle.

9. After receiving a GLP compliance certificate, a TF has to maintain its certification by paying the prescribed annual certification fee. The TF will be subject to surveillance inspection at 18 months (± 3 months) from the date of grant of GLP certification/ Re-certification, as specified in Document No. GLP-104 "Procedures of NGCMA Secretariat."

10. A TF, wishing to continue its GLP compliance status beyond the existing cycle, will have to submit a re-certification application, in the prescribed application form (GLP-102) for the subsequent certification cycle, along with the prescribed fee, at least 6 months prior to the expiry of the existing GLP certificate. The NGCMA will undertake an inspection for re-certification through a team of inspectors before the expiry of existing GLP certificate.

11. Pre-inspection would not be conducted for a certified TF as well as for TF certified by Monitoring Authorities of other OECD MAD adherent countries.

12. The validity of the existing GLP certificate can be extended by 3 months provided the TF has applied for re-certification at least 6 months before the expiry of existing GLP certificate and that the re-certification inspection has taken place before the expiry of existing GLP certificate. The extension of three months will be granted for reasons such as delay in approval process after the re-certification inspection or for a verification inspection to be conducted by NGCMA. If a verification inspection is to be conducted for the TF and the validity of existing GLP certificate is going to expire, the TF would be advised not to initiate any new GLP studies during this period. Further, in case the decision of non-grant of GLP re-certification is taken by the NGCMA, the date of removal of the TF from the National GLP Programme would be the date of re-certification inspection.

13. TF, entering into second or subsequent cycles of GLP certification, may note that Action Taken Report (ATR) after the inspection for re-certification should be submitted in time to enable the NGCMA to follow the approval process. In case the TF does not submit a satisfactory ATR within the stipulated time, the existing GLP certificate will lapse. The TF will then have to apply afresh.

14. Follow-up Actions for Pre-inspection:

a) The TF is required to take corrective actions, if any, and submit an ATR to NGCMA on deficiencies pointed out to them during the closing conference of the pre-inspection within 6 months of the conduct of pre-inspection. The TF should ensure that corrective actions have been completed before submission of ATR.

b) After receiving the ATR from the TF, NGCMA Secretariat will review it in consultation with the lead inspector.

c) If all the deficiencies have been addressed satisfactorily in the ATR, the NGCMA Secretariat will organize & conduct a final inspection.

d) If no ATR is received from the TF within 6 months, the TF will have to make a fresh application along with the prescribed application fee.

e) The formal report of pre-inspection is received by NGCMA from the inspection team within 45 days of conduct of the pre-inspection & is communicated to the TF thereafter.

15. Follow-up Actions for Final inspection:

a) The TF is required to take corrective actions, if any, and submit an ATR to NGCMA for the deficiencies pointed out to them during the closing conference of the final inspection within 45 days of completion of the inspection.

b) Final inspection report, along with ATR submitted by a TF, and the report of verification inspection, if conducted, are submitted to the Technical Committee

(TC) on GLP constituted by the NGCMA which, in turn, makes a recommendation for the award of GLP certificate to the concerned TF or re-inspection of the TF or obtain clarifications from the TF or rejection.

c) The recommendation of the TC on GLP is put up to Chairman, GLP Authority for appropriate decision.

d) If approved for grant of GLP certification, the TF is issued the GLP Certificate highlighting name and address of the TF, areas of expertise and validity of the certificate.

e) The final inspection report along with the recommendations of the TC on GLP and decision on grant of GLP certificate on otherwise is communicated to the TF.

16. A GLP-compliant TF under the National GLP Programme shall comply and operate in accordance with the OECD Principles of GLP and instructions/ rules/ guidelines issued by the NGCMA, if any. Further, the TF should immediately inform any changes in scope of GLP compliance, major change in organization, change in name/legal status etc. to NGCMA.

17. Surveillance inspection of TF is undertaken by the NGCMA usually midway through the period of validity of GLP certificate {18 months (± 3 months) from the date of grant of GLP certificate}. If TF desires to have GLP certification for any additional area/ facility, the same can also be sought during the surveillance visit by making a specific request in the prescribed Application form for GLP certificate, along with requisite fee. In addition to this, the TF would require to submit the following documents to NGCMA atleast 2 months before the completion of 18 months from the date of grant of GLP certification/ re-certification or as and when intimated by NGCMA {3 hard copies and a softcopy in CD form & by e-mail (PDF or MS Word version restricting the size to 10 MB)} of Application form (for additional scope), if applicable:

- Latest Organograms
- Latest Floor Plans
- List of Standard Operating Procedures (SOPs)
- List of Instruments/ Equipments including computerized systems
- Master Schedule since last GLP inspection

The findings of surveillance inspection are communicated to the TF during the closing conference. The TF is required to take corrective actions, if any and submit an ATR to the deficiencies pointed out to them within 45 days of conduct of the inspection to NGCMA. Surveillance inspection reports are communicated to the TF along with the recommendations of TC on GLP.

18. In addition to the above-mentioned inspections, NGCMA may also conduct inspection(s) or Study Audit(s), at the request of a Regulatory Authority (RA)/ GLP Compliance Monitoring Authority (CMA) of OECD MAD adherent country(ies) or Joint GLP

Inspections/ Study Audits with RA/CMA of OECD MAD adherent countries(ies). The inspection procedures of the NGCMA will be followed for such inspections. The inspection report will be forwarded to the concerned RA/ GLP CMA who sought such inspection or study audit(s), with a copy to the concerned TF.

19. The NGCMA reserves the right to conduct surprise inspections, if deemed necessary. Such inspections can be undertaken after the approval of Chairman, NGCMA. The TF will have to submit an ATR to the findings of the surprise inspection within 45 days of completion of the surprise inspection to the NGCMA. The surprise inspection report will be forwarded to the TF along with the decision of Chairman, GLP Authority on its GLP compliance status.

20. The TFM or its representative(s) have to be present during the opening and closing conferences. The list of observations of the GLP inspection will have to be signed by the TFM or its representative(s) and the inspection team.

21. In case serious deviations are found during a certification cycle, NGCMA may take appropriate actions which include, but are not limited to the following:

- Issuance of a statement giving details of the inadequacies or faults found, which might affect the validity of studies conducted by the TF;
- Issuance of a recommendation to a RA that a study be rejected
- Suspension of TF's GLP certification or study audit and/or withdrawal of the TF's GLP certification
- Informing the National RA or/and GLP CMA in other MAD adherent country(ies) about the inadequacies found & Action taken by NGCMA
- Requiring that a statement detailing the deviations be attached to specific study reports;
- Action through the courts, where warranted by circumstances and where legal/ administrative procedures so permit.

22. It is mandatory for a TF to maintain a master schedule which should contain details of all studies (GLP and Non-GLP) conducted by it. These details include study number, name of the test item (coded form is acceptable), name of the test system, type of study (acute, repeated dose, inhalation, dermal, etc), along with duration, name of the sponsor (coded name is acceptable), name of the study director, study initiation date, experiment start date, experiment completion date, study completion date and date of archiving the study-related documents/ specimens.

23. In case a TF is engaged in multi-site studies and tests, details about the test site, such as, location and address, management structure, type of studies being carried out and facilities available should be provided. The TF must ensure that the test site adheres to the OECD Principles of GLP, performs studies and tests accordingly & produce evidence to this effect. The TF may be asked to facilitate the visit of the inspection team to the test site, if required. In case the test site is outside India, the TF should have an evidence to show that it is GLP compliant.

24. A GLP compliant TF must have SOPs for all the activities being undertaken in the TF.

25. All study related data, including study plan, raw data, study report, samples of test and reference items and specimens of a GLP study must be archived in a manner that these can be accessed easily at a later date, if required. The period of archiving will usually be governed by the requirements of the sponsor and/or regulatory authority(ies). It is, however, recommended to maintain records for three cycles of GLP certification. The archive should be suitably designed so as to guard against risks due to fire, fungus, electrical short circuiting, theft, etc.

26. TF must read, understand and apply GLP principles as enunciated in OECD Principles of GLP, Document Numbers 1-17 and submit a statement to this effect to the NGCMA along with the application for GLP certification.

27. Status of each TF with regard to its compliance to OECD principles of GLP would be put up on the website of NGCMA www.indiaglp.gov.in.

28. The applicant TF shall be liable to pay the following:

(i) Application fee Rs. 25,000/-* per each area of expertise for which certification is sought.
(ii) Annual certification fee Rs. 25,000/- *
(iii) Actual expenditure for travel of inspection team visiting the TF to carry out different GLP inspections except surprise inspection. The travel expenses would be restricted to economy class Airfare/AC 2 Tier train fare. Boarding and lodging for the inspection team, including local transportation shall also be borne by the TF.

***Note:** Applicable taxes need to be added to the application and annual certification fee

29. The GLP compliance certificate is awarded to a division/ section/ laboratory/ department of a larger company/ organization, performing GLP studies/ tests. Hence GLP certificate will be valid only for the specified component of the company/ organization. In such a case, a clear relationship existing between the TF and the management of the company/ organization must be shown in the relevant documents and application for GLP certification. The management of the company/ organization must declare in the application for GLP certification that it seeks GLP compliance certificate in respect of the

TF mentioned in the application form for GLP certification and the TF should be clearly identified with suitable description, including floor plans and layout.

31. **Modifications in GLP Certificate during a GLP Certification Cycle**

a) Change in name of the TF

During a certification cycle, any change in name of the TF, along with merger/ takeover/ restructuring of the organization for any reason shall be communicated to NGCMA along with duly authenticated supporting documents, and the implications on the TF's compliance to OECD Principles of GLP. The supporting documents shall be reviewed and appropriate action will be initiated. If found satisfactory, new certificate with same validity as the previous certificate will be issued by NGCMA.

b) Extension in Scope

A TF wishing to extend the scope of GLP certification during a GLP certification cycle may do so by submitting a request for the same after atleast 3 months of grant of a GLP certificate or alongwith the documents submitted for a surveillance inspection to GLP Cell, QCI. The request should include submission of documentation for the requested extended area(s) i.e. Organograms, Floor plans, List of SOPs, List of equipment and Master schedule (with at least one archived study) in each of the extended area(s). In that case, an extension in scope inspection or the surveillance inspection, to include the extended scope of the TF in the Facility Inspection and Study Audits, can be conducted for the TF, as deemed necessary by NGCMA. The follow up actions on such inspections and approval process for extension of scope of GLP certification would be the same as for the process of grant of GLP certificate.

c) Reduction in Scope

Voluntary Reduction: A TF wishing to reduce its scope of activities covered in its GLP certificate may do so by voluntarily withdrawing the respective areas. A letter to this effect, stating the reasons for withdrawal of an area or reduced scope be submitted to Head, NGCMA by the TF. A list of GLP studies done by the TF in the respective area(s) which are to be withdrawn from GLP certification should also be submitted, clearly stating the GLP status of studies conducted by the TF in that area.

The information given by the TF would be examined by NGCMA Secretariat and put up for approval by Chairman, GLP Authority. After approval a new GLP certificate would be issued by NGCMA, omitting the respective area(s) of expertise.

Forced Reduction: A TF will have to demonstrate its competence to conduct GLP studies in a particular area of expertise wherein they have not conducted GLP studies for more than 1 year during a surveillance inspection. In case the TF fails to do so, the inspection report should mention the same. Thereafter, the case is considered by the TC

on GLP, whose recommendations are further referred to Chairman, GLP Authority for a final decision on the reduction in scope of GLP for the TF.

The validity of the revised GLP certificate, if applicable would be from the date of approval by Chairman, GLP Authority till the validity of the existing GLP certificate. The revised GLP certificate will supercede the earlier GLP certificate w.e.f. the date of issue of the former GLP certificate. The number of revised GLP certificate will have a suffix "A" to the earlier certificate number. Such as

Earlier GLP certificate number: GLP-XXX/YYYY
Revised GLP certificate number: GLP-XXXA/YYYY

Any information pertaining to reduction in scope of GLP compliance of a TF would be put up on the website of the NGCMA and also shared with OECD Working Group on GLP and concerned regulatory authorities, as applicable.

33. TF using computer systems for different activities should specify & list the computerized systems being used and the procedure being followed to maintain the security and integrity of computerized data.

34. TF can file a complaint/ grievance/ appeal against any adverse decision of NGCMA. The appeal shall be processed by the NGCMA in accordance with Document No. GLP-108 "Procedures for handling of Complaints, Grievances and Appeals".

35. All disputes, if any, arising out of NGCMA decisions that remain unresolved through mechanisms provided by NGCMA are subject to exclusive jurisdiction of the Courts at New Delhi and none other.

These Terms and Conditions should be submitted by the applicant TF along with the Application for GLP Certification/ re-certification, with the clause to be read as:

"I have read, understood and agree to abide to the above Terms & Conditions of NGCMA for obtaining and maintaining GLP certification by a test facility (GLP-101).

Signatures of TFM
Name:
Designation:
Date:

Approved for issue by:

(Signature with date) 23/6/16
Head, NGCMA